REMARKS

The Office Action of February 23, 2005, has been received and reviewed. Claims 1-7, 10, and 12-16 are currently under examination. Claims 8, 9, 11, and 17-24, while withdrawn, may be subject to rejoinder. Reconsideration is respectfully requested.

Rejoinder:

The applicants thank the Examiner for acknowledgement that claims 17, 21 and 22, Group II, may be rejoined upon allowance of a linking claim (page 3 of the Office Action mailed February 23, 2005). Further, applicants respectfully submit that claim 1 is generic for claims 8, 9, 11, 23, and 24 and thus applicants respectfully request that these claims be rejoined as claim 1 is believed to be in condition for allowance.

Rejection under 35 U.S.C. § 112, first paragraph:

Claims 1-7, 10, and 12-16 stand rejected under 35 U.S.C. § 112, first paragraph, as assertedly failing to comply with the written description requirement. At page 4 of the Final Office Action, it is alleged that "[t]he claims are rejected because the application lacks written descriptive support for the negative limitation excluding adenoviruses from the claimed methods."

Applicants respectfully assert that proper written description for the exclusion of adenoviruses is found in the specification. For instance, ¶ 44 of the specification recites "[t]he present invention discloses human immortalized cell lines . . . that are generally used . . . for the purpose of propagating, production and harvesting viruses *other than adenoviruses* . . ." (emphasis added). As such, applicants respectfully submit that support for the element excluding adenoviruses from claims 1-7, 10, and 12-16 is provided by the specification. Reconsideration and withdrawal of the rejection are thus respectfully requested.

Rejection under 35 U.S.C. § 103:

Claims 1-7, 10, 12, 13, and 16 stand rejected under 35 U.S.C. § 103 as assertedly being unpatentable over Burk *et al.* in view of Hateboer *et al.*

Claims 1-7, 10, 12-14, and 16 stand rejected under 35 U.S 103(a), as assertedly being

unpatentable over Burk *et al.* and Hateboer *et al.* as applied to claims 1-3, 5-7, 12, 13, and 16, and further in view of Lin *et al.* (J Virol Methods 88: 219-25).

Claims 1-7, and 12-16 stand rejected under 35 U.S.C. 103(a), as assertedly being unpatentable over Burk *et al.* and Hateboer *et al.* as applied to claims 1-3, 5-7, 12, 13, and 16, and further in view of Halliday *et al.* (WO 99/5 1776).

The applicants respectfully traverse the rejections for at least the following reasons. Each rejection relies on the combination of Burk *et al.* in view of Hateboer *et al.*, therefore, the applicants traverse the rejection based on this combination of references. It is to be understood that the additional references Halliday *et al.* and and Lin *et al.* do not add the missing elements asserted to be present in the combination of Burk *et al.* and Hateboer *et al.* Therefore, the applicants traverse the rejection based on this core combination, with the understanding that further discussion of Halliday *et al.* and Lin *et al.* is unnecessary.

The Office acknowledges that Burk *et al.* fails to disclose or suggest the use of a cell expressing an adenoviral E1 protein. The Office then asserts that because the cells of Burk *et al.* are similar to the cells of Hateboer *et al.* it would be obvious to a person of ordinary skill in the art that the cells of Hateboer *et al.* could be used in the method of Burk *et al.*

Applicants respectfully traverse the rejection, since, inter alia, there is no motivation to combine the references. Burk *et al.* teaches the use of hepatic cells to investigate hepatic viruses. Hateboer *et al.* teaches the use of adenovirus with cells they are known to infect (retinal cells). There is no teaching or suggestion in the references that would indicate that one can investigate viruses generally using cells that they are not known to normally infect. If one were to follow the teachings of Burk *et al.* and Hateboer *et al.*, one would investigate a virus through the use of cells that the virus is normally known to infect (hepatic cells for hepatoviruses (Burk *et al.*) and retinal cells for adenoviruses (Hateboer *et al.*). Thus, no motivation exists to use the E1 encoding cells of Hateboer *et al.* with the methods of investigating hepatocytes of Burk *et al.*.

In addition, the Examiner indicates that the applicants have not provided affirmative evidence of what would be expected in the art. Final Office Action at page 6. However, applicants respectfully assert that it is not the applicants' duty to show that the references teach away from the proposed combination. Indeed, it is the Examiner's duty to provide a proper

motivation to combine the cited references. *See* MPEP § 706.02(j). The Examiner notes, at page 6 of the Final Office Action, that Hateboer *et al.* is completely silent as to the utility of the cells therein for the replication of other viruses. Applicants respectfully assert that this silence of Hateboer *et al.* is a further indication that one would not be motivated to use the cells of Hateboer *et al.* for the replication of viruses other than adenovirus. One would have no motivation to use the cells of Hateboer *et al.* as it is not taught or suggested that they might be useful for such a purpose.

Additionally, the Examiner notes that Hateboer *et al.* "provides no teaching to indicate that the cells would not be useful in such methods." *Id.* However, the Examiner, as a basis for combining the reference, is required to provide motivation that indicates that one of skill in the art *would* find such cells useful in the claimed methods. Applicants respectfully submit that the Examiner's assertion that the reference does not teach away from the proposed combination does not, by implication, indicate that one of skill in the art would suggest the combination and find the cells of Hateboer *et al.* to be useful in the teachings of Burk *et al.*. As such, applicants respectfully submit that the Examiner has not provided a proper motivation to combine the references as required by 35 U.S.C. § 103.

Moreover, if one were to combine the teachings of Burk *et al.* with those of Hateboer *et al.*, the resulting combination would render Burk *et al.* unsatisfactory for its intended purpose. If a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then no suggestion or motivation exists to make the proposed modification. *In re Gordon*, 733 F.3d 900, 221 USPQ 1125 (Fed. Cir. 1984); *see also* MPEP § 2143.01.

The Examiner asserts that "Burk specifically teaches that the cells used in the methods disclosed therein may be transformed using oncogenic viral proteins." Final Office Action at page 5. Further, the Examiner asserts that "those in the art would have had a reasonable expectation that the adenoviral E1 proteins would be equally useful in the methods of Burk as the other identified viral oncogenes." *Id.* at page 6. Thus, if one were to combine the teachings of Burk *et al.* and Hateboer *et al.*, one would attempt to transform hepatocytes with adenoviral E1 proteins. However, contrary to the Examiners assertion, it is well known in the art that adenoviral E1 proteins are not useful for the transformation of the hepatocytes taught by Burk *et al.*. Gallimore et al. indicate that attempts to transform hepatocytes with E1 functions have been

unsuccessful. Gallimore et al., Anticancer Res., 6, 499-508, 1986, at page 5, column 1. As a result, if one combined the teachings of Burk *et al.* with those of Hateboer *et al.* in an attempt to practice the claimed methods, such a combination would be unsatisfactory for the intended purpose since the adenoviral E1 proteins of Hateboer *et al.* would be unsuccessful at transforming the hepatocytes of Burk *et al.*. For the foregoing reasons, applicants respectfully submit that no motivation exists to combine the references as is required for a rejection under 35 U.S.C. § 103(a). Reconsideration and withdrawal of the rejection of claims 1-7, 10 and 12-16 under 35 U.S.C. § 103(a) are thus respectfully requested.

In addition, "obvious to try" is not the standard under 35 U.S.C. § 103. It is obvious to try when one would have "to vary all parameters to try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no directions as to which of many possible choices is likely to be successful." *In re O'Farrell*, 853 F.2d 894, 903, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988).

Burk *et al.* teaches a large genus of possible genes that can be used to immortalize a cell; to wit "an oncogene effective to inhibit the normal cell-replication control mechanism(s) of the primary cells in culture." Burk *et al.* at page 9, lines 14-16. This large genus contains over 100 known genes. *See e.g.*, Bejamin Lewin, Genes V 1184 (Oxford University Press and Cell Press 1994). Further, where Burk *et al.* provides examples, adenovirus E1 is not mentioned among the 29 examples given. Burk *et al.* at Table 1. Of all these possible oncogenes, Burk *et al.* provides no direction as to which of these more than 100 possible choices is likely to be successful. The applicants respectfully submit that Examiner relies on impermissible hindsight to conclude that one would choose adenoviral E1 from the more than 100 possible choices. Consequently, the combination of Burk *et al.* and Hateboer *et al.* provides, at most, only that it might have been obvious to try the use of E1 in a cell according to the methods of the present invention. As obvious to try is not the standard under 35 U.S.C. § 103, however, applicants respectfully submit that the combination of Burk *et al.* and Hateboer *et al.* cannot make obvious claims 1-7, 10 and 12-16. *See, e.g., In re* Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). Reconsideration and withdrawal of the rejection of claims 1-7, 10 and 12-16 under 35 U.S.C. § 103(a) are respectfully requested.

CONCLUSION

At least claims 1-7, 10 and 12-16 are believed to be in condition for allowance. Should questions remain after consideration of the remarks herein that may be addressed by a telephone conference, the Office is kindly invited to contact the applicants' representative at the number provided herein.

Respectfully submitted,

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